K072411 # 1/4

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 20 2008

Submitters Name:

aap Implantate AG
Lorenzweg 5
12099 Berlin
Germany
Phone: +49 30 750 19 0
Fax: +49 30 750 19 111

Contact Name:

Dipl.-Ing. Marc Seegers
Lorenzweg 5
12099 Berlin
Germany
Phone: +49 30 750 19 192
Fax: +49 30 750 19 111
email: m.seegers@*aap*.de

Trade Name: *aap* Bone Plate and Screw Implants

Common/Usual Name: Bone fixation plate and screw

Classification Name: Plate, Fixation, Bone Screw, Fixation, Bone

Device Class: Class II

Product Code: 87 HRS
87 HWC

Classification: CFR Chapter I, Title 21 § 888.3030
CFR Chapter I, Title 21 § 888.3040

Review Panel: Orthopaedics

Performance Standards:

- Devices are manufactured according to cGMP's, applicable ASTM requirements, and applicable harmonised standards ISO 13485:2003.
- The aap Bone plates are manufactured from commercial pure Titanium (cpTi ASTM F67 or ISO 5832-2) and 316L Stainless Steel (ASTM F139 or ISO 5832-1).
- The *aap* Bone screws are manufactured from Titanium Alloy (ASTM F 136 or ISO 5832-3) and (ASTM F 138 or ISO 5832-1).

K072911 #2/4

Intended Use:

The *aap* bone plates and screws are provided non-sterile in a tray or separately packed. The devices are intended to treat fractures of various bones, including the clavicle, scapula, pelvis, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, and phalanges) according to the standard of the AO Foundation (AO Priciples of Fracture Management). All *aap* bone plates and screws are for single use only.

Contraindications

Inflammation, sepsis and osteomyelitis are absolute contraindications.

All applications that are not defined by the indications and the specialist literature are contraindicated.

All spinal fixation procedures.

In addition, surgical success can be adversely affected by:

- acute or chronic infections, local or systemic
- vascular, muscular or neurological pathologies that compromise the concerned extremity
- all concomitant pathologies that could affect the function of the implant.
- osteopathies with reduced bone substance such as severe osteoporosis
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.
- Known or suspected sensitivity to metal
- Corpulence: an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur.
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status.

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- the presence of tumors
- congenital abnormalities
- immunosuppressive pathologies
- increased sedimentation rates that cannot be explained by other pathologies
- increased leukocyte (WBC) count
- pronounced left shift in the differential leukocyte count.
- Untreated malfunction of the metabolism
- Joint destruction caused by haemophilia, tabes or after infections
- Instability of the joint ligaments

K072911 #3/9

Device Description:

The *aap* bone plate and screw implants are used for internal fixation of long and small bones. The plates are manufactured from commercial pure Titanium or Stainless Steel and the screws are manufactured from Titanium alloy or Stainless Steel.

Plates (in brackets corresponding screw diameters):

- 4.5 ACP Broad Plate (ø6,5mm/ ø4,5mm)
- 4.5 ACP Narrow Plate (ø6,5mm/ ø4,5mm)
- Straight Reconstruction Plate 4.5 (ø4,5mm)
- T-Plate 4.5 (ø6,5mm/ ø4,5mm)
- T-Buttress Plate 4.5 (ø6,5mm/ ø4,5mm)
- L-Buttress Plate 4.5 (ø6,5mm/ ø4,5mm)
- Spoon-Plate 4.5 (ø6,5mm/ ø4,5mm)
- 3.5 ACP Straight Plate (ø4.0mm/ ø3.5mm)
- 3.5 Straight Reconstruction Plate (ø3.5mm)
- 3.5 Cloverleaf Plate (ø4.0mm/ ø3.5mm)
- 3.5 T-Plate (ø4.0mm/ ø3.5mm)
- 3.5 T-Plate olique angled (ø4.0mm/ ø3.5mm)
- 3.5 1/3 Tubular Plate (ø4.0mm/ ø3.5mm)
- 2.7 Straight Plate (ø 2.7mm)
- 2.7 Straight Reconstruction Plate (ø 2.7mm)
- 2.7 Small T-Plate (ø 2.7mm)
- 2.7 1/4 Tubular Plate (ø 2.7mm)
- 2.0 Straight Mini-Fragment Plate (ø2.0mm)
- Mini-Fragment T-Plate 2.0 (ø2.0mm)
- Mini-Fragment with straight L-Shape 2.0 (ø2.0mm)
- Mini-Fragment with oblique L-Shape 2.0 (ø2.0mm)

Screws:

- Cortical Screw (ø1.5mm)
- Cortical Screw (ø2.0mm) and Cortical Screw selftapping (ø2.0mm)
- Cortical Screw (ø2.7mm) and Cortical Screw selftapping (ø2.7mm)
- Cortical Screw (ø3.5mm) and Cortical Screw selftapping (ø3.5mm)
- Cortical Screw (ø4.5mm) and Cortical Screw selftapping (ø4.5mm)
- Cancellous Screw (ø4.0mm) and Cancellous Screw (ø4.0mm) with short thread
- Cancellous Screw (ø6.5mm) with full thread
- Cancellous Screw (ø6.5mm) with 16mm thread
- Cancellous Screw (ø6.5mm) with 32mm thread

K073911 p 4

Predicate Devices for Substantial Equivalence:

The *aap* bone plates and screws are similar in size, material and intended use to

- Syntec-Taichung Bone Plate and Screw Implants (K983495)
- Synthes Sterile 2.7mm Reconstruction Plates (K974908)
- Synthes Bone Plates and Bone Screws for standard Osteosynthesis (Preamendment
- Stryker Trauma Plating System (K000636)
- Stryker Plating System Basic Fragment Set (K012162)

Comparision of the technological Characteristics of the device to the predicate legally marketed devices:

There are no significant differences between the *aap* Bone Plate and Screw Implants and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, materials and intended use.

Sterilisation Information:

The devices are distributed in non sterile, recommendations for sterilization are contained in package insert. Note: These devices are sterilised by end users utilizing the approved/outlined guidelines found in the AAMI Guideline "Good Hospital Practice: Steam Sterilisation and Sterility Assurance" and in ANSI/AAMI/ISO 11737 guidelines to achieve the acceptable Sterility Assurance Level (SAL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2008

aap Implantate AG
% Mr. Marc Seegers, Dipl.-Ing
Director, QA/RA
Lorenzweg 5
12099 Berlin
Germany

Re: K072411
Trade/Device Name: aap Bone Plates and Screw Implants
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 14, 2008
Received: March 17, 2008

Dear Mr. Seegers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072411

Device Name: *aap* Bone Plates and Screw Implants

Indications for Use:

The devices are intended to treat fractures of various bones, including the clavicle, scapula, pelvis, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, and phalanges) according to the standard of the AO Foundation (AO Principles of Fracture Management).

All *aap* bone plates and screws are for single use only and **are not intended for any spinal fixation procedures.**

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072411